REMARKS

In response to the Office Action mailed July 5, 2006, reconsideration is respectfully requested. Applicants have amended claims 1, 10 and 15, and claims 2, 5-7, 9 and 12-13 have been canceled. Claims 26-38 and 69-93 were previously canceled in the Preliminary Amendment mailed April 19, 2004, and the Examiner has withdrawn from examination claims 19-25, 39-68, and 94-101. No new matter has been added. The above amendments are not to be construed as acquiescence to the Examiner's stated grounds for rejection and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

The enclosed electronic and paper copies of the Sequence Listing include no new matter that goes beyond the original application as filed, but are supplied to fulfill the requirements as outlined in the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

Further, the above amendments to the specification, which merely direct the insertion of corrected sequence identifiers, include no matter that goes beyond the original application as filed. Applicants respectfully submit that the above-identified application is in compliance with 37 C.F.R. §§ 1.821-1.825.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-2, 5-7 and 18 stand rejected under 35 U.S.C. § 112, second paragraph, on the basis that the sequence recited in claim 1(B), Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2), is different than the sequence, Trp-Ala-Pro-Ile-Pro, listed as SEQ ID NO: 2 in the Sequence Listing.

Applicants respectfully traverse this rejection. The enclosed Sequence Listing has been amended to correct SEQ ID NO: 2 by adding the amino acid "Arg" at position one, which was disclosed on page 6, lines 24-25, of the originally filed application. The omission of the "Arg" from SEQ ID NO: 2 in the Sequence Listing was an inadvertent error and the addition of the "Arg" is not new matter as it was disclosed in the application as originally filed.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-2, 5-7, 9-15 and 18 stand rejected under 35 U.S.C. § 112, first paragraph. According to the Examiner, the specification, while being enabling for a cell adhesion modulating agent comprising a Trp-containing CAR sequence, wherein the CAR sequence is SEQ ID NO: 2, does not provide enablement for any and all cell adhesion modulating agents according to the claims.

Applicants respectfully traverse this rejection. As an initial matter, Applicants note that claims 2, 5-7, 9 and 12-13 have been canceled and claim 1 has been amended to be specifically drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Accordingly, the claimed invention is drawn specifically to compounds described and supported by Applicants' experimental demonstration in the specification as filed that SEQ ID NO: 2 can effectively inhibit cell adhesion.

Regarding the Examiner's comments that the modifications of claim 10 are not enabled, Applicants submit that such modifications are illustratively described in the specification and that these and other N- and C-terminal modifications can be readily made and used by the skilled artisan without undue experimentation. For example, at page 66, lines 16 to 23, the specification describes that modulating agents may contain "derivatives of common amino acids, such as amino acids having the C-terminal carboxylate esterified (*e.g.,* benzyl, methyl or ethyl ester) or amidated and/or having modifications of the N-terminal amino group (*e.g.,* acetylation or alkoxycarbonylation), with or without any of a wide variety of side-chain modifications and/or substitutions (*e.g.,* methylation, benzylation, t-butylation, tosylation, alkoxycarbonylation, and the like)." Further, the skilled artisan is fully aware of how to confirm that any such modified peptide modulating agents retain the function of inhibiting cell adhesion, using one or more illustrative assays described in the specification as filed and/or known in the art.

Regarding the Examiner's comments that claim 15, wherein the modulating agent further comprises a CAR sequence other than SEQ ID NO: 2, is not enabled, Applicants

respectfully disagree. Making and using CAR sequence from cell adhesion molecules other than the desmosomal CAR sequence of SEQ ID NO: 2 is extensively described in the specification as originally filed, e.g., at page 60, line 24 to page 63, line 18. As described therein, and as known in the art, CAR sequences have been identified and characterized for a wide variety of cell adhesion proteins. Accordingly, a skilled artisan would understand and expect that a modulating agent of the presently claimed invention may contain, in addition to a CAR sequence consisting essentially of RWAPIP (SEQ ID NO: 2), other CAR sequences and that the use of such other CAR sequences in a claimed modulating agent can serve to further inhibit cell adhesion and/or modulate a function mediated by the cell adhesion protein from which the other CAR sequence was derived.

Rejections Under 35 U.S.C. § 102

Claims 1-2, 5-6, 9-10 and 12 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO97/10258. According to the Examiner, the cited reference describes a compound that comprises regions of the desmosomal cadherin Dsc2 and Dsc3 which are Trp-containing and contain no more than 50 amino acid residues.

Applicants respectfully traverse. As set forth above, claim 1 has been amended to be specifically drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Accordingly, the claimed invention is drawn specifically to compounds described and supported by Applicants' experimental demonstration in the specification as filed that SEQ ID NO: 2 can effectively inhibit cell adhesion.

Further, the compounds as claimed are not described by the cited prior art. As noted by the Examiner, the reference teaches a "region" of desmosomal cadherins, but does not teach or suggest modulating agents as claimed, consisting essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2), much less that such agents can inhibit cell adhesion, as claimed by Applicants. Reconsideration is respectfully requested.

Claims 1-2, 9-10 and 12-13 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chidgey *et al.* (Developmental Dynamics 210:315-327, 1997). According to the Examiner, Chidgey *et al.* describes a compound comprising the N-terminus of mature Dsc, having a sequence WAPIP. The Examiner states that the amino acid sequence is Trp-containing, contains no more than 50 consecutive amino acid residues, and is present within a linear peptide.

Applicants respectfully traverse. As set forth above, claim 1 has been amended to be specifically drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Accordingly, the claimed invention is drawn specifically to compounds described and supported by Applicants' experimental demonstration in the specification as filed that SEQ ID NO: 2 can effectively inhibit cell adhesion.

This cited reference describes the expression pattern of Dsc3 during epithelial development; however, the cited reference does not teach a peptide modulating agent as claimed. The passage noted by the Examiner describes the design of amplification primers in the region of Dsc cDNA that "corresponds to a highly conserved protein sequence, WAPIP." However, nowhere does this passage, or this reference, describe any modulating agent consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2), much less that such an agent can inhibit cell adhesion, as claimed by Applicants. Reconsideration is respectfully requested.

Claims 1-2, 5, 7, 9, 10 and 12 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO94/21809. The cited reference allegedly teaches a 16 amino acid peptide of the sequence Thr-Val-Leu-Arg-Arg-Ala-Lys-Arg-Arg-Trp-Ala-Pro-Ile-Pro-Cys-Ser. According to the Examiner, the described sequence is Trp-containing, contains no more than 50 consecutive amino acid residues, and is present within a linear peptide.

Applicants respectfully traverse. As set forth above, claim 1 has been amended to be specifically drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Accordingly, the claimed invention is

drawn specifically to compounds described and supported by Applicants' experimental demonstration in the specification as filed that SEQ ID NO: 2 can effectively inhibit cell adhesion. Moreover, Applicants' claimed invention is neither taught nor suggested by WO94/21809. Although this reference describes a 16-mer peptide that comprises a sequence related to SEQ ID NO: 2, it does not teach or suggest any modulating agent consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2), much less that such an agent can inhibit cell adhesion, as claimed by Applicants. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1 and 10-11 stand rejected under 35 USC 103(a) as allegedly being obvious over WO97/10258, Chidgey *et al.* or WO94/21809, each in view of U.S. Patent No. 5,455,228 ("the '228 patent"). According to the Examiner, the teachings of the primary references have been discussed, and the '228 patent allegedly teaches the acetylation of the N-terminus is a traditional method for producing a peptide that resists cleavage by amino peptidase. The Examiner concludes that it would have been obvious for one of ordinary skill in the art to N-acetylate a peptide of WO97/10258, Chidgey *et al.* or WO94/21809, as taught by the '228 patent.

Applicants respectfully traverse. Claim 1 is drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Each of WO97/10258, Chidgey *et al.* and WO94/21809 fails to teach or suggest the elements of claim 1, for reasons discussed above in the context of the Examiner's rejections under 35 U.S.C. § 102. The '228 patent discusses N-acetylation as a means for inhibiting cleavage by aminopeptidase, but offers nothing in relation to Applicants' claimed modulating agents consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2). Thus, even if a skilled artisan were to N-acetylate a peptide of WO97/10258, Chidgey *et al.* or WO94/21809, as described by the '228 patent, the artisan would still not arrive at the invention claimed by Applicants. As both the primary references and the'228 patent fail to teach or suggest the elements of claim 1, or suggest any manner in which the references can be combined

to arrive at Applicants' claimed subject matter, the '228 patent does not remedy the already noted deficiencies of the primary references. Reconsideration is respectfully requested.

Claims 1 and 14 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over WO97/10258, Chidgey *et al.* or WO94/21809, each in view of US Patent No. 6,936,587 ("the '587 patent"). According to the Examiner, the teachings of the primary references have been discussed, and the '587 patent allegedly teaches that a peptide bound to a solid support can be used to enrich or purify specific antibodies. The Examiner concludes that it would have been obvious for one of ordinary skill in the art to link a peptide of WO97/10258, Chidgey *et al.* or WO94/21809, to a solid support, as taught by the '587 patent.

Applicants respectfully traverse. Claim 1 is drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Each of WO97/10258, Chidgey *et al.* and WO94/21809 fails to teach or suggest the elements of claim 1, for reasons discussed above in the context of the Examiner's rejections under 35 U.S.C. § 102. The '587 patent discusses the attachment of peptides to a solid support for purification purposes, but offers nothing in relation to Applicants' claimed modulating agents consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2). Even to the extent a skilled artisan were to attach a peptide of WO97/10258, Chidgey *et al.* or WO94/21809 to a solid support, as described by the '587 patent, the artisan would still not arrive at the invention claimed by Applicants. As both the primary references and the'587 patent fail to teach or suggest the elements of claim 1, or suggest any manner in which the references can be combined to arrive at Applicants' claimed subject matter, the '587 patent does not remedy the deficiencies of the primary references. Reconsideration is respectfully requested.

Claims 1 and 18 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over WO97/10258, Chidgey *et al.* or WO94/21809, each in view of US Patent No. 6,713,450 ("the '450 patent"). According to the Examiner, the teachings of the primary references have been discussed, and the '450 patent allegedly teaches synthetic peptides or conjugates thereof can be formulated as a composition using adjuvants, pharmaceutically acceptable carriers, excipients, etc. The Examiner concludes that it would have been obvious for

one of ordinary skill in the art to formulate a peptide of WO97/10258, Chidgey *et al.* or WO94/21809, into a composition using pharmaceutically acceptable carriers as taught by the '450 patent.

Applicants respectfully traverse. Claim 1 is drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). Each of WO97/10258, Chidgey *et al.* and WO94/21809 fails to teach or suggest the elements of claim 1, for reasons discussed above in the context of the Examiner's rejections under 35 U.S.C. § 102. The '450 patent discusses the formulation of a peptide in carriers, excipients and the like, but offers nothing in relation to Applicants' claimed modulating agents consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2). Thus, even to the extent a skilled artisan were to formulate a peptide of WO97/10258, Chidgey *et al.* or WO94/21809 in a manner described by the '450 patent, the artisan would still not arrive at the invention claimed by Applicants. As both the primary references and the'450 patent fail to teach or suggest the elements of claim 1, or suggest any manner in which the references can be combined to arrive at Applicants' claimed subject matter, the '450 patent does not remedy the deficiencies of the primary references. Reconsideration is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Favorable consideration is earnestly solicited.

Respectfully submitted,

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